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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,789	10/10/2003	Hoa La Wilhelm	KC-19204	1789

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Maxwell J. Petersen
Pauley Petersen & Erickson
Suite 365
2800 West Higgins Road
Hoffman Estates, IL 60195

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/683,789	**Applicant(s)** WILHELM ET AL.	
	Examiner Melanie Yu	**Art Unit** 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.
2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-26 and 28* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,3-26 and 28* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments and amendments filed December 13, 2004 and January 28, 2005 have been entered.

Status of the Claims

2. Claims 1, 3, 4, 10, 20, and 28 are currently amended. Claims 2 and 27 are canceled. Claims 1, 3-26 and 28 are currently pending.

Withdrawn Rejections

3. Rejection of claims 1-11, 14-20, 22-24 and 28 under 35 USC 102(e) have been withdrawn in view of Applicant's arguments and amendment. Rejections of claims 1-28 under 35 USC 112, second paragraph have been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 3-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claims 1, 10, 20, and 28 provides a negative limitation, excluding a hydrogen ion or ion aggregate from the mammalian substance to be detected. It is noted that the original specification on page 2, lines 8-13 discloses a hydrogen ion or ion

aggregate as a mammalian substance capable of being detected, but the specification does not disclose the negative limitation of excluding a hydrogen ion or ion aggregate from detection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3-11, 14-20, 22-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diehl et al. (US 2003/015830) in view of Ponce et al. (Critical Revision of Presumptive Tests for Bloodstains, Forensic Science Communications, Vol. 1, No. 2, July 1999) further in view of Rittersdorf et al. (US 3,917,452).

Diehl et al. teach a wearable article equipped with a multi-level alert system wherein three or more levels of a mammalian substance in a mammalian extract are detected, the article comprising: a substrate ([0034], lines 1-5); a target area on the substrate including first, second, and third sub-areas for receiving the mammalian extract (area where indicator is applied; [0034], lines 5-18); and a chemical detection system on the target area for detecting a first lower level of the mammalian substance, a second chemical composition in the second sub-area for detecting a second higher level of the mammalian substance, and a third chemical composition in the third sub-area for detecting a third level of the mammalian substance (Fig. 5; Fig. 6; [0028]; [0029], lines 14-39), wherein the chemical detection system comprises a different chemical composition on the first, second, and third sub-areas ([0028]; [0029], lines 14-26). Detection is performed by the chemical composition on the substrate, after which a signal (color change) is initiated and is emitted by each sub-area in response to a respective level of the mammalian substance (Fig. 5; Fig. 6; [0029], lines 22-29). The first and second signals can be compared to quantify the first level of the mammalian substance ([0029], lines 36-42). Diehl et al. fail to teach a mammalian substance not being a hydrogen ion or ion aggregate.

Ponce et al. teach semiporous filter paper with a first chemical composition comprising phenolphthalein, a second chemical composition comprising o-tolidine, and a third chemical composition comprising leucomalachite (Materials and Methods, reagents) in order to test for false results in blood detection using reagents that detect different levels of blood in a sample (Evaluation of the Results, paragraph 3), but fails to provide motivation to include the chemical compositions in the wearable article of Diehl et al.

However, Rittersdorf et al. teach that the detection of blood in urine, feces, and vomit allows for diagnosis of hemorrhages in the stomach, intestines, and urinary tract (col. 1, lines 8-13 and 30-34).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the wearable article as taught by Diehl et al., the compositions to detect blood as taught by Ponce et al., in order to provide a multi-level alert system capable of detecting small amounts of blood to diagnose hemorrhages as taught by Rittersdorf et al.

Regarding claims 6-9 Diehl et al. teach the wearable article being a personal care absorbent article (diaper, [0015], lines 20-24), a medical absorbent article (bandage, [0015], lines 20-24), an athletic absorbent article (underwear, [0015], lines 20-24), a nonabsorbent article (belt, [0014], lines 4-11), a garment (underwear, [0015], lines 20-24), or an article of clothing (underwear, [0014], lines 4-11).

With respect to claims 23 and 24, Diehl et al. teach the wearable article wherein the first, second, and third sub-areas comprise strips, adjacent shapes, numbers, symbols, letters, or words ([0028], lines 8-11).

3. Claims 10, 12, 13, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Springer et al. (US 6,617,488) in view of Ponce et al. (Critical Revision of Presumptive Tests for Bloodstains, Forensic Science Communications, Vol. 1, No. 2, July 1999) further in view of Rittersdorf et al. (US 3,917,452).

Springer et al. teach a wearable article equipped with a multi-level alert system for detecting, and initiating and emitting a signal in response to three or more levels of a mammalian substance in a mammalian extract, the wearable article comprising: a substrate (col. 8, lines 15-23), a target area on the substrate comprising first, second, and third sub-areas (col. 7, lines 13-20 and 36-39) in the form of concentric shapes (bullseye, col. 10, lines 39-40), and a chemical detection system on the target area which detects and initiates a first, second, and third signal, in response to a respective first, second, and third level of mammalian substance (col. 7, lines 13-20 and 28-35). Springer et al. also teach the chemical compositions in the sub-areas adapted to detect different levels of pH in the mammalian substance (col. 7, lines 13-26). However, Springer et al. fail to teach the mammalian substance excluding a hydrogen ion and an ion aggregate.

Ponce et al. teach semiporous filter paper with a first chemical composition comprising phenolphthalein, a second chemical composition comprising o-tolidine, and a third chemical composition comprising leucomalachite (Materials and Methods, reagents) in order to test for false results in blood detection using reagents that detect different levels of blood in a sample

(Evaluation of the Results, paragraph 3), but fails to provide motivation to include the chemical compositions in the wearable article of Springer et al.

However, Rittersdorf et al. teach that the detection of blood in urine, feces, and vomit allows for diagnosis of hemorrhages in the stomach, intestines, and urinary tract (col. 1, lines 8-13 and 30-34).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the wearable article as taught by Springer et al., the compositions to detect blood as taught by Ponce et al., in order to provide a multi-level alert system capable of detecting small amounts of blood to diagnose hemorrhages as taught by Rittersdorf et al.

With respect to claims 12 and 13, Springer et al. teach a wearable article wherein the first and second signal comprise a respective light or a respective sound in response to a level of pH (col. 10, lines 13-20). Spring et al. teach an electrochemical indicator, including a pH sensor, comprising the compositions of the first, second, and third sub-area and an electrochemical cell (col. 8, lines 44-52). The pH sensor provides an electrical signal, such as an electric potential that depends on pH, and emits a visual indication (light) or an audible signal (sound).

Response to Arguments

4. Applicant's arguments and amendments, see pages 10 and 11, filed December 13, 2004, with respect to the rejection(s)of claim(s) 1-24, 27 and 28 under 35 USC 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the change in scope of the claims in the amendment filed January 28, 2005, which excludes detection of hydrogen ion or

ion aggregate. A new rejection under 35 USC 103(a) has been made in view of the exclusion of hydrogen ions and ion aggregates from detection.

5. Applicant's arguments filed December 13, 2004 on pages 11 and 12 with respect to the rejections of claims 25 and 26 under 35 USC 103(a) have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness to combine Diehl et al. and Ponce et al. is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Ponce et al. is relied upon for the compositions used for detecting different levels of blood, and is not relied upon for being a wearable article. Diehl et al. is relied upon for being a wearable article, and can detect different levels of blood when the compositions of Ponce et al. are incorporated into the article. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ponce et al. does not provide motivation to combine with Diehl et al. or Springer et al. However, Rittersdorf et al. teach that detection of blood in urine allows for diagnosis of

hemorrhages. Therefore, it would have been obvious to alter the device of Diehl et al. and Springer et al. in order to detect blood, instead of pH, in urine as taught by Rittersdorf et al. The article would not be rendered inoperable because the articles of Diehl et al. and Springer et al. would be altered with the compositions of Ponce et al. to detect different levels of blood in order to diagnose hemorrhages instead of detecting different levels of pH to diagnose dehydration.

6. Applicant's arguments filed January 28, 2005 have been fully considered but they are not persuasive. Applicant cited case law and MPEP 2173.05(i) to support the negative limitation included in the amendment which refer to 35 USC 112, first paragraph, scope of enablement rejections, wherein the negative limitation did not require a scope of enablement rejection. The cited does not provide sufficient support for amending claims 1, 10, 20 and 28 to recite a negative limitation that is not included in the specification. Furthermore, "any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement (see MPEP 2173.05(i)).

Conclusion

No claims are allowed

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

2/7/05